

# Notice of Allowability

Application No.

10/012,202

Examiner

Humera N Sheikh

Applicant(s)

HIRSH, MARK

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 19 February 2004.
2. ☒ The allowed claim(s) is/are 1-29.
3. ☐ The drawings filed on \_\_\_\_\_ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All b) ☐ Some\* c) ☐ None of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

## Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date 06/01/04.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_.

THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600

## **DETAILED ACTION**

### **Status of Application**

Receipt of the Appeal Brief filed 02/19/04 is acknowledged.

Claims 1-29 are pending. Claims 1-29 are allowed.

### **EXAMINER'S AMENDMENT**

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Patrea L. Pabst on 05/28/04.

The application has been amended as follows:

#### **In the Claims:**

**Claim 1**, line 7, after the word "ingestion", the phrase "wherein the delayed release portion is achieved by coating a core or granulations with at least one delayed release control polymer" has been added.

***Allowable Subject Matter***

Claims 1-29 are allowed.

The following is an examiner's statement of reasons for allowance:

The instant invention is drawn to a biphasic antihistamine composition in daily oral uni-dosage or divided dosage form which comprises: (a) a therapeutically effective amount of a sedating antihistamine to inhibit antihistamine release for a duration of about 4 to 12 hours, and (b) a therapeutically effective amount of non-sedating antihistamine to inhibit antihistamine release for a duration of 10 to 20 hours, with a delayed release 6 to 10 hours after ingestion, wherein the delayed release portion is achieved by coating a core or granulations with at least one delayed release control polymer.

The primary reason for allowance is that the inclusion of the specific limitation of how the delayed release portion is achieved (i.e., by coating a core or granulations) was agreed upon in a telephone interview with Applicant(s) attorney. It was noted in the interview that the prior art does not teach a biphasic antihistamine composition comprising a delayed release non-sedating antihistamine in combination with a sedating antihistamine, whereby the delayed release portion is obtained by coating a core or granulations with at least one delayed release control polymer.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should

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preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."


### **Correspondence**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday from 7:00A.M. to 4:30P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

*hns*  
June 01, 2003

  
THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
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